USE OF DATABASES IN RISK ASSESSMENT FOR THE OPERATION AND MAINTENANCE OF MEDICAL EQUIPMENT

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Abstract: *This paper presents the design and application of a relational database system to support risk assessment in the operation and maintenance of medical equipment. The proposed system enables systematic registration of equipment, tracking of maintenance, repairs, calibration, and inspections, as well as recording of responsible personnel and vendors. By providing traceability, trend analysis, and real-time monitoring of failures, the database facilitates early detection of hazards, improves decision-making on equipment replacement, enhances staff training, and contributes to cost-effective budget planning.*

Keywords: *Risk Assessment, Medical Equipment, Database, Equipment Lifecycle, Maintenance and Repair, Safety*

1. Introduction

Risk assessment is the process of making decisions about the acceptability of a risk based on risk analysis, regulatory provisions [1], [2] and taking into account factors such as technical achievements, environmental, psychological, economic and social aspects. Risk assessment is the use of available information to identify hazardous events and to determine the elements of risk [3]. The main elements of risk are probability, severity of damage to life and health, and exposure.

Risk assessment is a mandatory process required by the regulatory framework for ensuring health and safety at work and medical standards. When it is used for internal control, it allows early to detect the possible problems and to improve management of the medical establishment in which the medical equipment is used.

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The risks, connected with the medical devices, are various and can be systematized into several main categories, each of which requires a specific approach to identification, control, and minimization – Table 1.

Table 1

The groups of risks using medical devices

Technical risks	Biological and radiation risks	Electrical and mechanical risks	Organizational risks:
✓ Physical ✓ Fields ✓ Software or hardware defects in the medical equipment, ✓ Improper operation, ✓ Equipment shutdown during a critical procedure	✓ Equipment, emitting ionizing radiation (e.g. X-ray, CT scan), ✓ Contact with body fluids ✓ Microorganisms	✓ Incorrect connection, ✓ Insulation damage, ✓ Direct and indirect contact, ✓ Failed protection, ✓ Unsecured moving or rotating parts, ✓ Overloading, etc.	✓ Insufficient maintenance, ✓ Lack of training, ✓ Gaps in documentation ✓ Incorrect distribution of responsibilities,

Regulation No. 5 of May 11, 1999, on the procedures and intervals for conducting risk assessments [2] examines with the risk assessment. There are additional national requirements related to the registration, certification and technical support of medical equipment, developed by the Ministry of Health.

Regulatory national and international documents [4], [5], [6] govern the use and maintenance of medical equipment to provide a framework within which the maintenance and operation of medical equipment must guarantee safety, traceability and compliance with good practices. European directives such as Regulation (EU) 2017/745 on medical devices [7] and [8] impose a high standard of traceability, safety and risk management.

ISO 14971 [6] provides a comprehensive framework for risk management of medical devices from design to decommissioning. It includes hazard identification, analysis of the likelihood of occurrence, assessment of the severity of consequences, and methods for controlling and monitoring the residual risk.

2. Aim

The aim of the paper is to propose a relational database structure for the purposes of risk assessment in the operation and maintenance of medical equipment. The internal database

there is a capability to improve and identify potential hazards and determine the probability of appearance. This is an important phase in which potential sources of danger are discovered.

3. Method

Identifying potential hazards connected to the medical devices and technology is the process of establishing the existence of a hazard and determining its features, which are the likelihood and severity of possible injury.

Discovering potential sources of danger - technical defects, human errors, organizational shortcomings, external factors, as well as interactions between different devices or systems is an important phase.

An internal database system is designed to support technical and administrative staff in hospitals and clinical facilities supporting the following stages of risk assessment - identifying hazards and determining the likelihood of harm occurring.

A well-functioning internal database relation type of database should cover the following modules: Maintenance, Inspection, Repair and Calibration Forms; Automatic reminders, schedules and annual reports; Trend analysis capability; Traceability of activities performed; Analysis of frequently faulty appliances; Support in management decisions; Modules for equipment registration, problem reporting and maintenance calendars.

The database, created by the autors, uses MS Access environment. It consists of the following basic structural elements:

1. Equipment registration with a unique identifier and technical characteristics, location etc.
2. Maintenance, check, calibration and repair activity on the equipment.
3. Schedules and reports.
4. Staff, responsible people
5. Manufacturers and vendors

The database can help to fulfill trend analysis – extract and aggregate data to identify recurring problems. Devices with high failure rates, most frequently replaced components, and devices generating the highest repair costs can be identified. This allows for more informed budget planning, targeted staff training, and replacement of inefficient equipment.

Using the database can trace all activities related to maintenance, repairs and calibration of the equipment. Forms and reports record all events in detail - from the submitted request to the completed intervention.

Through specially designed queries and reports (e.g. "Recurring Problems"), the database enables automated analysis of equipment that frequently requires repair or maintenance. This facilitates the identification of technical weaknesses, unprofitable

equipment or the need for replacement. The data can be used for early warning of risks and better planning of future investments.

4. Results

As a tool for applied risk assessment and management, a database in MS Access was developed with the structure shown in Fig. 1. Table 2 describes all the tables in the database, with their fields, primary and foreign (external) keys.

Table 2

List of tables in the database

Table	Primary key - identifier	External key	Fields in tables
Equipment	EquipmentID	-	Device name Serial number Type Acquisition date Manufacturer Technical characteristics
Maintenance	MaintenanceID	EquipmentID Responsible personnel	Activity type Planned date Responsible person Notes
Repair	RepairID	EquipmentID Responsible technician	Repair date Description of the problem Actions taken Used parts Responsible technician Costs
Support request	RequestID	EquipmentID Submitted by	Submitted face Submission date Description Status
Checks	InspectionID	EquipmentID Responsible inspector	Check date Condition Results Recommendations Responsible inspector
Request	RequestID	EquipmentID Submitted by	Submission date Submitted face Description Status Date of decision
Calibration	CalibrationID	EquipmentID	Calibration date Calibration organization Certificate number Result Next calibration
Schedule	ScheduleID	EquipmentID Responsible person	Activity type Planned date

Table	Primary key - identifier	External key	Fields in tables
			Responsible person Notes
Staff	StaffID	-	Name Position Qualification Contacts

Fig. 1. Main menu of the relational database

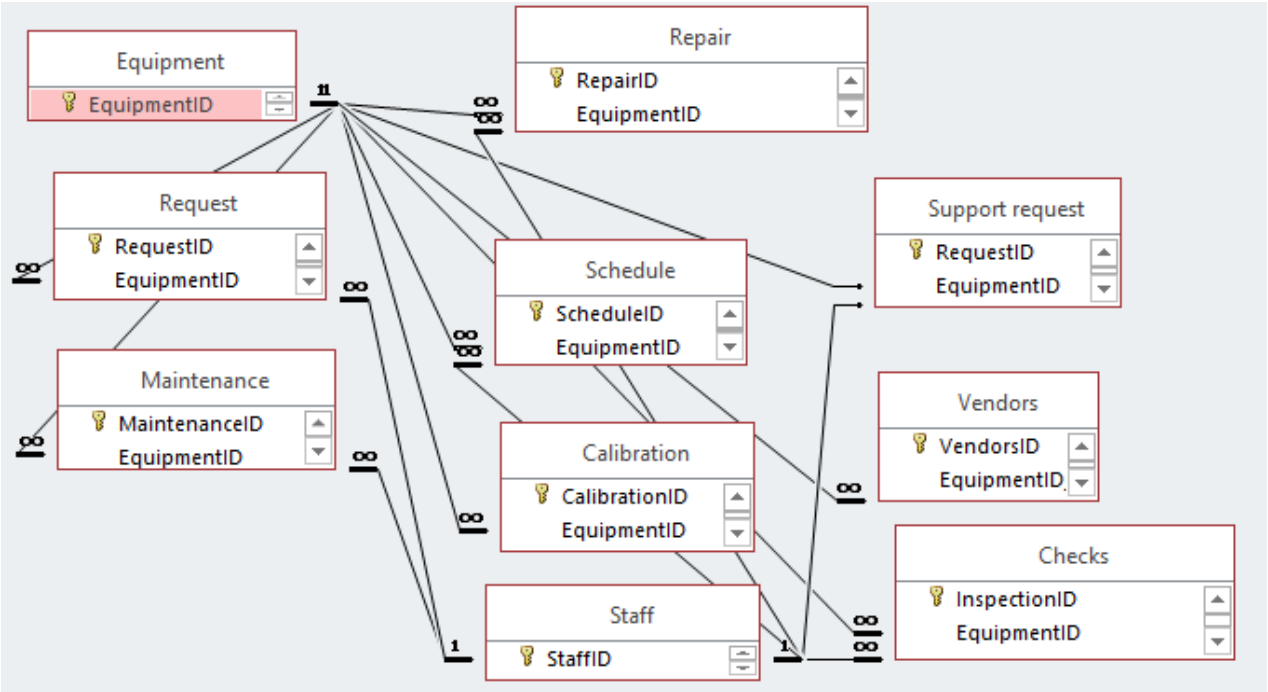

Fig. 2. Graphical representation of the tables and the relationships between them

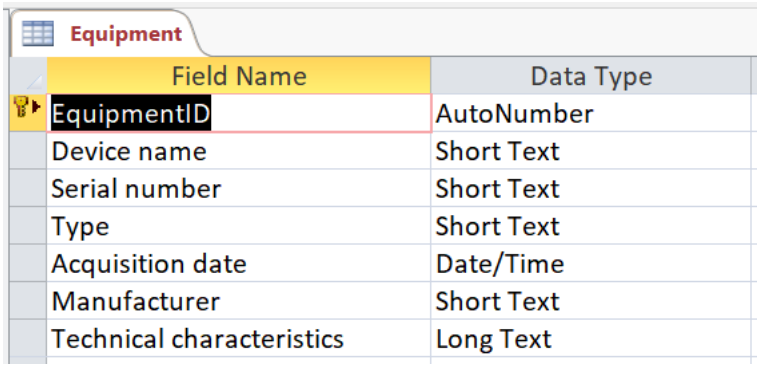

Fig.3. Design View of Table Equipment

Table 3 shows an example as Datasheet View of Table Equipment – the devices are examples without specific brands.

Table 3

An example as Datasheet View of Table Equipment

Equipment						
Equipment ID	**Device name**	**Serial number**	**Type**	**Acquisition date**	**Manufacturer**	**Technical characteristics**
1	X-ray machine	XR2022-01	X-ray	15.1.2022	Name of Manufacturer	125kV, digital detector, mobile
2	MRI Scanner GE 1.5T	MRI-9001	MRI	10.6.2021	Name of Manufacturer	1.5T, 16 channels, helium cooling
3	Ultrasound device	US-9002	Ultrasound	5.3.2023	Name of Manufacturer	7.5 MHz, 3D
4	ECG device BTL-08	ECG-223	ECG	20.11.2022	Name of Manufacturer	12-channel, printer, 500 records memory
5	Dental X-ray	XR-03	X-ray	14.9.2020	Name of Manufacturer	Panoramic system, high resolution, low dose
6	Infusion Pump	INF-122	Pump	1.12.2021	Name of Manufacturer	Dual channel, alarm system, LCD display
7	Anesthesia Machine	DR-300	Anesthesia	18.4.2022	Name of Manufacturer	Electronic control, gas monitoring
8	Hematology Analyzer	SYS-07	Analyzer	30.1.2023	Name of Manufacturer	3-Diff, automatic sampling, Ethernet interface
9	Endoscope	END-100	Endoscope	12.7.2021	Name of Manufacturer	HD image, flexible tube, waterproof
10	Defibrillator	DEF-777	Defibrillator	25.2.2022	Name of Manufacturer	Manual mode, ECG, rechargeable battery

Table 4 shows an example as Datasheet View of Table Shedule.

Table 4

An example as Datasheet View of Table Schedule

Schedule					
Schedule ID	**Equipment ID**	**Activity type**	**Planned date**	**Responsible person**	**Notes**
1	1	Maintenance	1.6.2025	2	Pre-Summer Preventive Inspection
2	2	Check	15.5.2025	3	Post-Repair Inspection
3	3	Calibration	1.6.2025	1	Annual Scheduled Calibration
5	4	Check	20.5.2025	5	Post-Component Replacement Inspection
6	5	Maintenance	1.6.2025.	4	Annual Maintenance
7	6	Calibration	15.6.2025	6	Pre-Seasonal Inspection
8	7	Maintenance	1.7.2025	3	After Accuracy Issue
9	8	Check	10.8.2025	7	Annual Schedule
10	9	Calibration	5.9.2025.	2	Battery Replacement and Function Test
11	10	Maintenance	1.10.2025	1	re-Summer Preventive Inspection

The benefits of using an internal database relate to:

- ✓ In the event of a fault, a repair request can be submitted in real time. This will allow technicians to react quickly and without delay. At the same time, the database will collect information about the faults occurring and their frequency, which is very useful information for risk assessment.
- ✓ Registered repairs, inspections or calibration in the database (date, responsible person, description of the activity, resources etc.) ensure good traceability of the activity performed according to the person who performed it. It is important to the following stage of risk assessment – probability and exposure.
- ✓ The database, through proper requests, can give information about repeated problems. It may be useful for decision making to replace certain equipment, to train additionally staff, etc. It also improves safety, reducing the number of incidents with patients or staff.
- ✓ The database allows for centralized and structured information for each device – purchase date, last repairs, technical condition, scheduled inspections. This not only facilitates daily work but also guarantees a high level of transparency and traceability, which is key during an internal audit or accreditation review.

- ✓ The system makes it possible to identify devices with recurring failures; eequipment that need more frequent maintenance, locations with problematic devices.
- ✓ The database information for the frequency of failures and repair costs is useful to improve budget planning and cost efficiency. In addition to planning new investments, optimizing the maintenance, which leads to extending the life of the equipment.
- ✓ Support in management decisions

The system provides summarized information and annual reports (e.g. "Annual Maintenance Summary", "Maintenance Schedule"), which serve as a basis for making informed management decisions. The system supports the management process by collecting, systematizing and analyzing data related to the maintenance and operation of the equipment. Management can use the information from the database to prioritize budget expenditures (such as tracking which equipment needs replacement due to frequent problems and repairs), optimize maintenance logistics (by better matching the load schedule), as well as monitor the implementation of regulatory requirements related to annual prophylaxis and calibration, and finally, reduces subjectivity and unsystematic data collection. The presence of a centralized database also supports accountability and traceability, which allows tracking the effectiveness of maintenance and the responsibilities of specific employees or suppliers. This achieves a higher level of control, efficiency and long-term sustainability.

The above-mentioned advantages can guarantee quantitative and qualitative risk assessment.

Conclusion

In conclusion, the integration of modern information solutions into the risk assessment and management process contributes to higher safety, reduced operating costs and extended life cycle of medical equipment. It is recommended that such systems be introduced as standard practice in medical institutions, especially in departments with high technical workload, such as imaging diagnostics. This approach guarantees higher quality medical services and sustainable development of the health system.

References

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[4] Medical Devices Act., State Gazette No. 46, 2007.

[5] Official Journal of the European Union, European Parliament. , 2007.

[6] ISO 14971:2019, Geneva, 2019.